Application No.: 10/023,584 Docket No.: PF112P1D2

REMARKS

Claims 1-110 are pending.

Provisional Election With Traverse

The Examiner has issued a Restriction Requirement separating pending claims 1 to 110 into 10 groups. See, Paper No. 9, page 2. To comply with the pending election requirement, Applicants herein provisionally elect, with traverse, the claims currently restricted to Group I (i.e., claims 1-19 and 22-50); drawn to an antibody to various fragments of SEQ ID NO:2, as well as cells and hybridomas. Applicants respectfully traverse the present election requirement.

In particular, Applicants traverse the restriction of claims drawn to an antibody to various fragments of SEQ ID NO:2, as well as cells and hybridomas (Group I) from claims drawn to an antibody to various fragments or forms of ATCC Deposit No. 97149, as well as cells and hybridomas (Group III).

Applicants respectfully submit that the Examiner has not provided sufficient reasons and/or examples to support his conclusion that the inventions are distinct. For example, the Examiner merely states that inventions I and III are "independent and distinct, each from each other, they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged." (See, Paper No. 9, page 2).

Pursuant to the M.P.E.P. § 803.01, when issuing a Restriction Requirement "[t]he Examiner must provide reasons and/or examples to support conclusions." However, the Examiner has not indicated how the inventions are independent and distinct, apart from providing a definition of independent and distinct. Specifically, the Examiner has not demonstrated how the products "possess characteristic differences in structure and function" or how "each has an independent utility that is distinct... which cannot be exchanged."

Applicants respectfully submit that the antibodies of Groups I and III do not, in fact, "possess characteristic differences in structure and function" nor do they have "an independent utility that is distinct... which cannot be exchanged." As the Examiner has acknowledged, the nucleic acid sequence of SEQ ID NO:1 and the deduced amino acid sequence of SEQ ID NO:2 were obtained by sequencing the cDNA clone deposited as ATCC Deposit No. 97149. (*See*, Paper No. 9, lines 10-11). Consequently, the group of antibodies that bind to the polypeptide of

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SEQ ID NO:2 would significantly overlap the group of antibodies that bind to the polypeptide of ATCC Deposit No. 97149, in structure, function and utility.

Additionally, the Examiner must demonstrate that there would be a serious burden to examine subject matter of all the Groups. *See*, M.P.E.P. § 803.02. Applicants submit that to search and examine the subject matter of all the Groups together, and in particular, to search Groups I and III simultaneously, would not entail a serious burden. As discussed above, the nucleic acid sequence of SEQ ID NO:1 and the deduced amino acid sequence of SEQ ID NO:2 were obtained by sequencing the cDNA clone deposited as ATCC Deposit No. 97149. Consequently, the group of antibodies that bind to the polypeptide of SEQ ID NO:2 would significantly overlap the group of antibodies that bind to the polypeptide of ATCC Deposit No. 97149. Consequently, a search for an antibody that binds SEQ ID NO:2 would clearly provide useful information for antibodies that bind ATCC Deposit No. 97149.

Thus, in view of M.P.E.P. § 803, the claims of <u>at least</u> Groups I and III should be searched and examined in the subject application. Accordingly, Applicants respectfully request that the restriction requirement under 35 U.S.C § 121, in particular with respect to Groups I and III, be reconsidered and withdrawn and the claims be examined in one application.

Furthermore, if the restriction requirement is maintained, Applicants request rejoinder of the claims of Groups II an IV-X once the claims of Groups I and III are found allowable. In light of the decisions in <u>In re Ochiai</u>, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and <u>In re Brouwer</u>, 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996), a notice was published in the Official Gazette which set forth new guidelines for the treatment of product and process claims. *See* 1184 OG 86 (March 26, 1996). Specifically, the notice states that:

in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim.

Id. Accordingly, if claims of Groups I and III are found allowable, Applicants respectfully request that the claims of Groups II and IV-X be rejoined and examined for patentability. See also M.P.E.P. § 821.04.

The Examiner has also required Applicants to elect one fragment of SEQ ID NO:2 or ATCC Deposit No. 97149 to be searched from the independent claims. While Applicants

strongly disagree with the instant requirement, in order to be fully responsive, Applicants provisionally elect, with traverse, the fragment of amino acid residues –46 to 373 (i.e., claim 1(a)). Applicants reserve the right to file one or more divisional applications directed to non-elected species should the election of species requirement be made final as a result of no generic claim being held allowable. Additionally, Applicants retain the right to petition from either the prior restriction requirement or the instant election of species requirement under 37 C.F.R. § 1.144.

With respect to the election of species requirement made by the Examiner, Applicants respectfully disagree and traverse. M.P.E.P. § 809.02(d) indicates that

Where only generic claims are presented, no restriction can be required except in those applications where the generic claims recite <u>such a multiplicity of species</u> that an unduly extensive and burdensome search is necessary. See MPEP § 808.01(a).

Applicants respectfully submit that the claims do not recite "such a multiplicity of species that an unduly extensive and burdensome search is necessary." In the present situation, Applicants respectfully assert that a search of the antibodies that bind a protein consisting of amino acid residues –46 to 373 of SEQ ID NO:2 will include antibodies that bind to any of the other fragments. Applicants respectfully wish to point out to the Examiner that the other fragments are included within the sequence of amino acids –46 to 373 of SEQ ID NO:2.

Furthermore, many, if not most, publications disclosing antibodies to a protein do not disclose the particular amino acid sequence to which those antibodies specifically bind. As such, the search will require a text search using the term "antibody" and the known names for the protein of the invention, as well as a sequence-based search on the protein of the invention. Since such a search will encompass all of the species envisioned by the Examiner, it cannot be a serious burden to search and examine all of the recited fragments. Nor would such a search be "unduly extensive and burdensome" as contemplated by M.P.E.P. §§ 808.01(a) and 809.02(d).

Accordingly, the instant election of species requirement should be reconsidered and withdrawn.

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CONCLUSION

Applicants respectfully request that the above-made remarks be entered and made of record in the file history of the instant application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: August 22, 2003

Respectfully submitted,

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